

These claims, at the very least, are comparable to various aspects of new claims 141-163, 164-177, and 283-294 (Chart A). Consequently, they comprise material originally presented prior to the request under 37 C.F.R. § 1.129(a) and therefore must be considered on their merits.

Furthermore, claims 19, 21, 26, 27-34, 49, 117, and 120 were pending on October 18, 1995 and July 9, 1996 but were not rejected in the Office Actions issued on at least one of these dates. These claims recited, e.g., specific dosages and administration of a chemotherapeutic or radiotherapeutic agent. Thus, the subject matter of such claims has evidently been examined and apparently deemed free of the prior art and allowable. Corresponding claims, e.g., 164, 167, 168, 170, 178, 283, 285, etc., therefore are allowable, as well (Chart B). The recitation in these claims of *additional* (but examined) aspects not recited in the original claims does not change their allowability.

Respectfully submitted,

Richard M. Lebovitz (Reg. No. 37,067)
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza I
2200 Clarendon Boulevard, Suite 1400
Arlington, VA 22201
(703) 812-5317
Internet Address: lebovitz@mwzb.com

Filed: May 2, 1997

RML:dm46:PROVI2.RES

PROVI 2

Chart A

13. **A method of treating cancer in a mammal having cancer comprising administering systemically to said mammal a Newcastle Disease Virus in an amount which alone is cytolytic or alone is cytotoxic to said cancer.**
 14. The method of Claim 13 wherein the cancer is a solid tumor.
 15. The method of Claim 13 wherein the cancer is a carcinoma.
 16. The method of Claim 13 wherein the cancer is a sarcoma.
 17. The method of Claim 13 wherein the cancer is selected from the group consisting of fibrosarcoma, synovial carsoma, colon carcinoma, breast carcinoma, prostate carcinoma, lung carcinoma, cervical carcinoma, neuroblastoma, glioblastoma, and melanoma.
 18. The method of Claim 13 wherein the cancer is selected from the group consisting of colon carcinoma, breast carcinoma, prostate carcinoma, lung carcinoma and glioblastoma.
 23. The method of Claim 13 wherein the virus is a mesogenic strain of Newcastle Disease Virus.
 24. The method of Claim 13 wherein the virus is Newcastle Disease Virus strain M.
 48. A method according to claim 13, wherein the effective amount of NDV results in regression of said cancer.
 134. A method according to claim 13, wherein said virus is administered at a site other than directly into a tumor of said cancer.
 35. The article of manufacture of Claim 33 wherein the virus is a mesogenic strain of Newcastle Disease Virus.
141. **A method of treating cancer in a mammal having cancer comprising administering to said mammal a mesogenic Newcastle disease virus in an amount which alone is cytolytic to said cancer. (142-163)**
164. **A method of treating cancer in a mammal having cancer comprising administering systemically to said mammal a Newcastle disease virus in an amount which alone is cytolytic to said cancer and results in regression of a tumor of said cancer. (165-177)**

36. The article of manufacture of Claim 34, wherein the virus is Newcastle Disease Virus strain M.
38. A method of treating cancer in a mammal having cancer comprising administering to said mammal, at a site other than directly into a tumor of said cancer, a Newcastle Disease Virus in an amount which alone is cytolytic or alone is cytotoxic to said cancer.
64. A method according to claim 38, wherein said virus is mesogenic.
67. A method according to claim 38, wherein said virus is strain M.
69. A method according to claim 38, wherein the effective amount of NDV results in regression of said cancer.
43. A method of treating cancer in a mammal having cancer comprising administering to said mammal an effective amount of a mesogenic Newcastle Disease Virus which alone is effective in treating said cancer.
106. A method according to claim 43, wherein said virus is administered systemically.
107. A method according to claim 43, wherein said amount of virus is 4×10^8 PFU/kg.
108. A method according to claim 43, wherein said virus is strain M.
111. A method according to claim 43, wherein the effective amount of NDV results in regression of said cancer.
125. A method according to claim 43, wherein the amount of virus administered is at least 4×10^9 PFU/kg.
133. A method according to claim 43, wherein the amount of virus administered is at least 4×10^9 PFU/kg.
140. A method according to claim 43, wherein said virus is administered at a site other than directly into a tumor of said cancer.
141. A method of treating cancer in a mammal having cancer comprising administering to said mammal a mesogenic Newcastle disease virus in an amount which alone is cytolytic to said cancer. (142-163)

RML.xml46:PROVID.CL2

PROVI 2

Chart B

19. The method of Claim 13 wherein at least 4×10^8 PFU of the virus is administered to the mammal per kilogram of body weight of the mammal.

167. A method of claim 164, wherein said amount of virus is at least 4×10^8 PFU/kg.

164. **A method of treating cancer in a mammal having cancer comprising administering systemically to said mammal a Newcastle disease virus in an amount which alone is cytolytic to said cancer and results in regression of a tumor of said cancer.**
Note additional recitation of "regression" as in examined claim 48.

283. **A method of treating cancer in a human having cancer comprising administering systemically to said human at least 4×10^8 PFU/kg of a Newcastle disease virus, which amount is alone is cytolytic to said cancer.**

168. A method of claim 164, wherein said amount of virus is at least 4×10^9 PFU/kg.

21. The method of Claim 13 wherein at least 4×10^9 PFU of the virus is administered to the mammal per kilogram of body weight of the mammal.

26. The method of Claim 25 wherein the compound is a retinoic acid.

27. A method of detecting cancer cells in a mammal comprising administering newcastle Disease Virus to the mammal and detecting the virus bound to the cancer cells.

28. The method of Claim 27 wherein the virus is labeled with a detectable label.

29. The method of Claim 27 wherein a labeled component that specifically binds to the virus is administered to the mammal to allow for detection of the virus bound to the cancer cells.

30. An imaging agent for detecting cancer comprising Newcastle Disease Virus labeled with a detectable label.

31. The imaging agent of Claim 30 wherein said detectable label is a radioisotope.

32. A method of detecting cancer cells in a mammal comprising administering Newcastle Disease Virus to the mammal and subsequently measuring the quantity of said virus in a body fluid or tissue of the mammal as an indication of the presence of cancer cells in the mammal.

33. An article of manufacture, comprising:
a container;
a label on said container; and
a composition contained within said container;
wherein:
the composition is effective for treating or

PROVI 2

Chart B

detecting cancer in a mammal having cancer,
said label indicates that the composition can be
used for treating or detecting cancer, and
the active agent in said composition comprises
Newcastle Disease Virus.

34. The article of manufacture of Claim 33 wherein
said label further indicates directions for the in vitro and/or
in vivo use of said composition.

49. A method according to claim 13, further
comprising administering a chemotherapeutic or
radiotherapeutic agent.

117. A method according to claim 38, wherein said
amount of virus is at least
 4×10^8 PFU/kg.

120. A method according to claim 38, wherein the
amount of virus administered is at least 4×10^9 PFU/kg.

170. A method of claim 164, further comprising
administering radiation or a chemotherapeutic agent.

178. A method of treating cancer in a mammal having
cancer comprising administering to said mammal
an amount of Newcastle disease virus and
radiation or a chemotherapeutic agent, wherein
the amount of virus is alone cytolytic to said
cancer and results in regression of a tumor of
said cancer.

Note additional recitation of "regression" as in
examined claim 48.

268. A method of treating cancer in a mammal having
cancer comprising administering to said mammal
at least 4×10^8 PFU/kg of a Newcastle disease
virus, which amount is alone is cytolytic to said
cancer, and administering radiation or a
chemotherapeutic agent. (269-282)
Note additional recitation of dose.

283. A method of treating cancer in a human having
cancer comprising administering systemically to
said human at least 4×10^8 PFU/kg of a
Newcastle disease virus, which amount is alone is
cytolytic to said cancer.

285. A method of claim 284, wherein said amount of
virus is at least 4×10^9 PFU/kg.

RML:dm46:PROVI2.RES